Appln No.: 09/828,624
Amendment Dated: November 6, 2003
Reply to Office Action of June 13, 2003

REMARKS/ARGUMENTS

This is in response to the Office Action mailed June 13, 2003 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Applicants request an extension of time sufficient to make this paper timely, and enclose the appropriate fee. The Commissioner is authorized to charge any additional fees or credit any overpayments to Deposit Account No. 15-0610.

Claim 17 which was objected to under 37 CFR § 11.75 has been cancelled.

Claims 18 and 24 have been amended in view of the Examiner's remarks to correct the clerical errors.

The Examiner rejected claims 18-35 under 35 USC § 112, second paragraph as indefinite, citing several bases for the rejection. Each of these bases is addressed below.

(1) To the extent that the statement of the first ground for rejection can be understood, it is believed that the Examiner is asserting that Applicants must state in the independent claim what the gonadotropin is. If this is the case, then it is not apparent why this rejection is applied to all of the claims, including claims such as claims 19-25 which specifically recite FSH as the gonadotropin. Clarification of the rejection in a non-final office action is therefore requested if the rejection is not withdrawn.

Applicants would point out, however, that the standard for definiteness is whether a person skilled in the art, having read the specification, can determine the scope of the claims. The Examiner's statement that "all forms of gonadotropom (sic) are not representative of a menopausal condition" is not relevant, because these forms are not being claimed. What is being claimed is a test methodology where a gonadotropin is tested that has forms that are indicative of the menopausal state.

(2) Claim 18 has been amended in accordance with the Examiner's suggestion to include a reference back to step (a) in step (b).

(3) The Examiner states that claims18-22, 24-27 are indefinite because "no correlation of test results is determined from the comparing step." Step (c) in claim 18 states that "a difference or similarity between the results of the two assays is indicative of whether the human female individual is pre-menopausal or post-menopausal." The remainder of the claim requires performance of two assays. Both assays are for the same gonadotropin, but they (as is apparent from reading the specification) produce different results in from the first assay in at

least one menopausal states because of different specificity for the different forms of the gonadotropin. Note that on page 5, lines 3-7 of the application, it states that the assays "can be modulated such that in a non-menopausal state both assays give rise to a similar signal in terms of a particular colour or colour intensity, whereas in a menopausal state the second assay produces a discernably different colour or colour intensity." The reverse modulation is equally valid, such that a similarity in assay result indicates one state and a difference indicates the other. This is what claim 18 says, and a person skilled in the art would have no difficulty understanding this scope.

(4) The Examiner states that claims 23 and 28 are indefinite because of the references to a ratio. Applicants respectfully traverse this rejection. In response to the Examiner's first inquiry, it does not matter which number is the numerator and which the denominator as long as it is consistent with any standard to which it is compared. Further, a ratio of 1/1 (or 1) is indicative of similarity, which as discussed above, is a valid indicator in the assay of the invention.

(5) The Examiner rejected claim 31. Claim 31 has been amended to change the word "for" to "produced by" to make it clear that the signals combined by the means for combining are the signals produced by the two signal producing means. Beyond this, however, Applicants are at a loss as to the basis for the rejection. The Examiner seems to be arguing that the signal producing means are not required in the claimed device, but this ignores the fact that they are expressly recited in the claims. Further, the Examiner's assertion that the standard "means plus function" phrasing "means for combining" is in the future tense is not understood. Withdrawal of the rejection or a complete explanation of the basis for the rejection are requested.

(6) The Examiner rejected claim 32 based on the phrase "signal indicative of follicle stimulating hormone." Applicants submit that despite cross-reactivity which may exist, signals using FSH-specific reagents are still useful, and indeed used. Indeed, the monoclonal antibodies disclosed in this application are useful for just this purpose. As to the Examiner's question "what 'provided' means results in the recited indication?, Applicants understand this question to be a query as to the means disclosed to comply with ¶ 6 of section 112, notwithstanding the citation of only ¶2. Applicants direct the Examiner's attention to the specification as a whole, including in particular the assays as described at Page 6, line 10 - Page 8, line 11 and in the Examples. As to the question of what reagent or reagents are present as part of the claimed device, a person skilled in the art would understand that the reagents are those which will detect two different forms of FSH in the manner set forth in claim 31. Specific identification of reagent species is not required for definiteness.

(7) The Examiner rejected claims 33 and 35 as indefinite because ot eh phrase "produce a signal as a result of binding in a detection zone." The Examiner correctly states that

claims 31 and 32, from which calims 33 and 35 depend, do not comprise a detection zone, and that there is therefore a lack of antecedent basis. Applicants point out, however, that claims 33 and 35 refer to a detection zone, not the detection zone. Thus, the basis for this rejection is unclear, as there is no suggestion in the claim that there is a previously recited zone. Further the Examiner has not stated why a person skilled in the art would have difficulty understanding what is being claimed.

(8) The Examiner also rejected claims 33 and 35 stating that the phrase "of a labeled specific binding reagent with a particulate direct label" was unclear. The Examiner asked "which of the two signal producing systems comprises a direct particulate label." Applicants submit that the claim as presented clearly indicated that both systems do, but has amended the claim to make this even more explicit. As to the remainder of the Examiner's questions, it is not clear what the basis for these questions is. Claims 33 and 35 (as amended) each clearly state that "the first and second gonadotropin-responsive signal producing means each produce a signal as a result of binding in a detection zone of a labeled specific binding reagent with a particulate direct label." Why the Examiner is asking about additional reagents or third labeling means is unclear. Furthermore, the claims recite two signal producing means. There may of course be more, since it is a comprising claim, but that has nothing to do with the limitations of claims 33 and 35.

(9) Claim 34 has been amended to depend from claim 33.

In view of the foregoing remarks, Applicants submit that the rejections under 35 USC § 112, second paragraph, should be withdrawn. If any portion of the rejection is maintained, however, Applicants respectfully remind that Examiner that "it is incumbent on the Examiner to establish that one having ordinary skill in the art would not have been able to determine the scope of protection defined by the claim when read in light of the specification." *In re Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (POBAI 1989). The rejections presented in this Office Action and traversed by Applicants do not meet this standard. Accordingly, if the rejection is maintained, it should be only in a **non-final** action, and it should include an explanation of why the claim as presented is not understandable by a person skilled in the art who has read the specification.

The Examiner rejected claims 18, 26 and 27 as anticipated by Niccoli et al. The Examiner asserts that Niccoli discloses "the claimed invention directed to a method of testing for a menopausal condition in a human." However, Niccoli does not disclose a test for menopausal condition but merely reports on test results using different antibodies directed to lutropin. In fact, the paper does not have anything to do with testing for menopausal condition and the data in Table 1 of the reference indicate that such a test would be unlikely to work for this purpose. A comparison of the results are the two post-menopausal women tested shows huge variability in the results, and for several tests results which are both above and below the values for normal women using the same assay kit.

Furthermore, the Examiner has not considered all of the words, and thus all of the limitations in the claims when applying the reference. Step (a) of claim 18 reads

> obtaining a gonadotropin-containing sample from the human female individual, **wherein the gonadotropin present in the sample exists in a plurality of different forms, and wherein the form or forms in which the gonadotropin exists is different depending on whether or not a menopausal condition exists in the human female individual.**

The Examiner has improperly ignored the portion of this step set forth in bold above. This same tactic is applied with respect to step(b) of claim 18. This step (as amended) reads:

> performing contemporaneous first and second assays on the sample obtained in step (a), **said first assay producing an indication of the gonadotropin that is independent of the whether the individual is pre- or post-menopausal, and said second assay producing an indication of the gonadotropin that differs depending on whether the human female individual is pre-menopausal or post-menopausal.**

Again, the Examiner has improperly ignored the bold portion of the claim limitation. There is no indication that any combination of kits tested by Niccoli would meet the limitations of this claim.

Finally, step (c) reads:

> comparing the results of the first and second assays, **wherein a difference or similarity between the results of the two assays is indicative of whether the human female individual is pre-menopausal or post-menopausal.**

The mere fact that a comparison of assay results is done in Niccoli does not meet this limitation, because this comparison is not used as an indication of, and does not apparently provide an indication of the menopausal state of the individual tested.

Anticipation requires that each and every element of a claim is found in the single cited reference. The Examiner's failure to even mention substantial limitations in the rejected claims, including the reason that the method is performed, and the clear absence of any teaching of these limitations in the Niccoli reference make it apparent that this rejection is in error and should be withdrawn.

The Examiner used the same sort of selective reading of the claim to support the rejectio

of claims 18 and 19 as anticipated to Matikainen et al. This reference does not teach a method for assessing menopausal state. The tests performed do not meet the limitations of the claims. While two tests are performed, one is a test for bioactivity, while the other is a test for immunoreactivity. There is no indication that these tests discriminate in the manner indicated in the rejected claims, i.e., that one of the assays produces "an indication of the gonadotropin that is independent of the whether the individual is pre- or post-menopausal," and that the other assay produces "an indication of the gonadotropin that differs depending on whether the human female individual is pre-menopausal or post-menopausal." For these reasons, the rejection of claims 18 and 19 as anticipated by Matikainen should also be withdrawn.

In view of the amendments and arguments made herein, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

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